

Evaluating Intense Rehabilitative Therapies With and Without Acupuncture for Children With Cerebral Palsy: A Randomized Controlled Trial

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ABSTRACT. Duncan B, Shen K, Zou L-P, Han T-L, Lu Z-L, Zheng H, Walsh M, Venker C, Su Y, Schnyer R, Caspi O. Evaluating intense rehabilitative therapies with and without acupuncture for children with cerebral palsy: a randomized controlled trial. *Arch Phys Med Rehabil* 2012;93:808-15.

Objective: To compare the outcomes of conventional therapies (physical, occupational, and hydrotherapies) plus acupuncture with those without acupuncture when administered intensely in the management of children with spastic cerebral palsy (CP).

Design: Evaluation-blind, prospective randomized controlled trial.

Setting: Therapies and video-recorded assessments at a children's hospital in Beijing, China, and blind scoring and data analyses at a university in the United States.

Participants: Children (N=75), 12 to 72 months of age, with spastic CP.

Interventions: Intensely administered (5 times per week for 12wk) physical therapy, occupational therapy, and hydrotherapy either with acupuncture (group 1) or without acupuncture (group 2). To satisfy standard of care, group 2 subsequently received acupuncture (weeks 16–28).

Main Outcome Measures: The Gross Motor Function Measure (GMFM)-66 and the Pediatric Evaluation of Disability Inventory (PEDI) assessments at 0, 4, 8, 12, 16, and 28 weeks.

Results: At the end of 12 weeks, there was no statistically significant difference between the 2 groups, but when group 2 received acupuncture (16–28wk) there was a shift toward improvement in the GMFM-66 and the PEDI-Functional Skills Self-Care and Mobility domain. When groups were combined, statistically significant improvements after intense therapies occurred from baseline to 12 weeks for each outcome measure at each Gross Motor Function Classification System (GMFCS) level. After adjusting for expected normative matu-

ration gains based on age, the GMFM gains for children with GMFCS II level was statistically significant ($P<.05$) with a mean gain of 6.5 versus a predicted gain of 3.4.

Conclusions: Intense early administered rehabilitation improves function in children with spastic CP. The contribution from acupuncture was unclear. Children's response varied widely, suggesting the importance of defining clinical profiles that identify which children might benefit most. Further research should explore how this approach might apply in the U.S.

Key Words: Acupuncture therapy; Cerebral palsy; Rehabilitation.

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CEREBRAL PALSY (CP) is a disorder of movement and posture causing activity limitations attributed to nonprogressive insults to the developing fetal or infant brain. Motor disorders are often accompanied by disturbances of sensation, cognition, communication, perception, behavior, and seizures.¹ Children with mild involvement often improve, whereas those with more severe insults may require invasive and extensive surgical procedures.

CP is one of the most common pediatric neurologic and developmental disorders in the U.S. with an estimated rate of 3.6 per 1000 live births.² In 2004, the estimated lifetime total U.S. health care cost for persons with CP was \$921,000.³ The medical, psychosocial, and economic consequences of CP remain significant personal, family, and public health issues.

Current standard conventional therapies concentrate on improving function and minimizing complications. In western countries, standard therapies usually include individualized weekly or biweekly sessions of physical therapy (PT), with or without occupational therapy (OT), and in some children

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List of Abbreviations

| | |
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| BCH | Beijing Children's Hospital |
| CI | confidence interval |
| CP | cerebral palsy |
| GMFCS | Gross Motor Function Classification System |
| GMFM | Gross Motor Function Measure |
| HT | hydrotherapy |
| OT | occupational therapy |
| PEDI | Pediatric Evaluation of Disability Inventory |
| PEDI-FS | Pediatric Evaluation of Disability Inventory-Functional Skills |
| PT | physical therapy |
| RCT | randomized controlled trial |
| UA | University of Arizona |

speech therapy is added.⁴ In contrast, the standard of care for children with CP in China is a package of care that incorporates both western therapies (PT/OT), hydrotherapy (HT), plus components of traditional Chinese medicine: acupuncture and herbal baths. Children are prescribed an individualized rehabilitative program, but in China the diagnosis is often made earlier than in the U.S.; therapies are initiated as soon as the diagnosis is made, and are administered more intensely than in western countries: each therapy is ≥ 30 minutes 5 times per week for 12 weeks (60 sessions each).

Literature on brain plasticity gives theoretical reasoning that supports the Chinese approach. A young brain is more adaptable than an older brain: there is less myelin in the young brain and myelin has inhibitory influence on nerve regeneration; and trophic factors that stimulate nerve growth are in greatest abundance in the young.⁵ Because the reorganization and regrowth of neural tissue is use-dependent,^{6,7} and repetitive activity stimulates neural growth,⁸ early and intense therapies should have value.

The Chinese Biology Medicine database contains numerous reports comparing the western approach with the Chinese therapeutic package; most studies report that the Chinese approach is superior in improving function in children with spastic CP. These reports suggest that acupuncture is an essential component of the package.⁹⁻¹² However, the majority of these studies suffer from methodologic inadequacies and few have been subjected to rigorous scientific scrutiny.

The objective of this study was to compare the outcomes of the Chinese package of rehabilitation (PT/OT/HT plus acupuncture) with that achieved with more conventional therapies (PT/OT/HT without acupuncture). To satisfy Chinese standard of care, and to meet expectation of families, it was considered neither ethical nor pragmatic to randomize children to receive therapies with lesser intensity mimicking U.S. rehabilitation. Therefore, a direct comparison of the western therapeutic approach (1–2 times per wk) to the Chinese approach (5 times per wk) could not be done. Instead, we assessed the effectiveness of intense therapies for children with spastic CP by comparing the results seen in the children enrolled in this study with documented developmental growth trajectories of children receiving routine therapies in Canada.¹³

METHODS

This 3-year, prospective, parallel, 2-arm, evaluation-blind randomized controlled trial (RCT) was an international collaboration between The Beijing Children's Hospital (BCH), where participant recruitment, intervention therapies, videotaped recording, and data collection took place, and the University of Arizona (UA), where blind scoring of the videotaped evaluations, data analyses, and logistic support took place. The study was funded by the Arizona Biomedical Research Commission and was approved by the UA Institutional Review Board and the BCH Human Subjects Committee.

Participants

Children 12 to 72 months of age with spastic CP confirmed by 2 pediatric neurologists and with any of the 5 Gross Motor Function Classification System (GMFCS)¹⁴ severity levels were eligible. The central nervous system insult must have occurred prior to birth, during delivery, or within the neonatal period. Conditions that might be contraindications for acupuncture or might compromise the evaluation procedures (blindness or deafness) excluded participation. Children who had had treatments (physiotherapies or traditional Chinese medicines) prior to the study were not excluded, but to avoid confounders,

the use of muscle relaxants or herbal therapies were not allowed during the study period.

Randomization

After obtaining the parents' signed consent, children were randomized off-site into 1 of 2 groups using a standard computerized stratified, size-varying, block randomization procedure (<http://www.randomizer.org/index.htm>). The randomization, based on 2 strata (age, 12–36mo or 36–72mo; CP severity, GMFCS level I–III or IV–V) was not disclosed to the BCH team until completion of the baseline evaluation. In accordance with the Consolidated Standards of Reporting Trials statement, both generation of unbiased allocation sequence and allocation concealment were maintained.¹⁵

Intervention

Children were followed for 28 weeks. Following the standard practice in China, children, along with a family member, generally the mother, resided in the hospital for the duration of the intervention. Group 1 received acupuncture concurrently with intense conventional therapies (PT/OT/HT) 5 times each week for 12 consecutive weeks, followed by 16 weeks receiving no formal therapies. Group 2 received only the intense conventional therapies without acupuncture for the initial 12 weeks, followed by a nonintervention period of 4 weeks when children in both groups returned to their homes. To satisfy standard of care for CP in China, group 2 returned to BCH and received 12 weeks of the acupuncture they missed as their only formal therapy; group 1 returned to BCH for assessment at 16 and 28 weeks (fig 1). Thus, group 1 children resided in the hospital for 12 weeks; group 2 children resided in the hospital for 24 weeks with a 4-week break between each 12-week treatment period.

PT, OT, and HT sessions were approximately 30 minutes each. Specific functional goals were determined according to each child's level of motor development. Gentle muscle stretching, passive and active range of motion, active positioning to improve balance and postural awareness, and manual facilitation of specific functional activities were incorporated as related to the child's treatment goals. PT focused on gross motor tasks: rolling, sitting, transitions, independent sitting, walking, and stair climbing. OT focused on fine motor tasks: eye-hand coordination and activities of daily living. HT was basically relaxation in warm water.

Acupuncture treatments followed standard procedures. The selection of the specific acupuncture regimen for each subject was based on a comprehensive acupuncture study manual developed specifically for this RCT so as to maintain balance between standardization of intervention and individualization of treatment.¹⁶ Treatment sessions started with a short massage

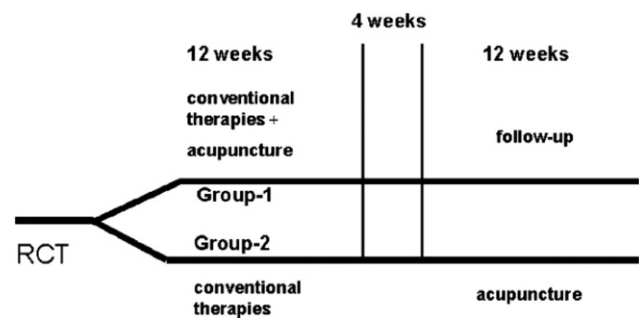


Fig 1. The overall study design.

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